CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM
15.C Small Business Technology Transfer (STTR)
Proposal Submission Instructions

The approved FY15.C topic included in the Chemical and Biological Defense (CBD) Small Business Technology Transfer (STTR) Program is listed below. Offerors responding to this Solicitation must follow all general instructions provided in the Department of Defense (DoD) Program Solicitation. Specific CBD STTR requirements that add to or deviate from the DoD Program Solicitation instructions are provided below with references to the appropriate section of the DoD Solicitation.

General Information

In response to Congressional interest in the readiness and effectiveness of U.S. Nuclear, Biological and Chemical (NBC) warfare defenses, Title XVII of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103-160) required the Department of Defense (DoD) to consolidate management and oversight of the Chemical and Biological Defense (CBD) Program into a single office – Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs. The Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD), Defense Threat Reduction Agency (DTRA) provides the management for the Science and Technology component of the Chemical and Biological Defense Program. Technologies developed under the Small Business Technology Transfer (STTR) Program have the potential to transition to the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) if the appropriate level of technology maturity has been demonstrated. The JSTO-CBD Science & Technology programs and initiatives are improving defensive capabilities against Chemical and Biological Weapons of Mass Destruction. The STTR portion of the CBD Program is managed by the JSTO-CBD.

The mission of the Chemical and Biological Defense Program is to ensure that the U.S. Military has the capability to operate effectively and decisively in the face of chemical or biological warfare threats at home or abroad. Numerously factors continually influence the program and its technology development priorities. Improved defensive capabilities are essential in order to mitigate the impact of Chemical and Biological Weapons. The U.S. military requires the finest state-of-the-art equipment and instrumentation available that permits our warfighters to detect to warn and avoid contamination, if possible – and to be able to sustain operations in a potentially contaminated environment. Further information regarding the DoD Joint Chemical and Biological Defense Program is available at the DoD Chemical Biological Defense homepage at http://www.acq.osd.mil/cp.

The overall objective of the CBD STTR Program is to improve the transition or transfer of innovative Chem-Bio technologies to the end user – the warfighter – in addition to commercializing technologies within the private sector for mutual benefit. The CBD STTR Program targets those technology efforts that maximize a strong defensive posture in a biological or chemical environment using passive and active means as deterrents. These technologies include chemical and biological detection for both point and stand-off capabilities; individual and collective protection; hazard mitigation (decontamination); information systems technology to include but not limited to modeling and simulation and operational effects & mitigation; medical pre-treatments (e.g., vaccine development and delivery); medical diagnostics & disease surveillance; and medical therapeutics (chemical countermeasures and biological countermeasures).

Submitting Your Phase I CBD STTR Proposal

Your entire proposal submission (consisting of a Proposal Cover Sheet, the Technical Volume, Cost Volume, and Company Commercialization Report) must be submitted electronically through the DoD SBIR/STTR Proposal Submission system located at https://sbir.defensebusiness.org/. A hardcopy is NOT required and will not be accepted by the Chemical and Biological Defense STTR Program. Hand or electronic signature on the proposal is also NOT required.

The Proposal Technical Volume must be 20 pages or less in length. The Cover Sheet, Cost Volume and Company Commercialization Report do not count against the 20-page Proposal Technical Volume page limit. Pages in excess of this length will not be evaluated and will not be considered for review. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

The Company Commercialization Report must be prepared through the Proposal Submission site and the Report will be included with your electronic submission; however, the Company Commercialization Report does not count against the proposal page limit. Update your commercialization information if it has not been updated in the past year. Note that improper handling of the Commercialization Report may result in the proposal being substantially delayed and that information provided may have a direct impact on the review of the proposal. Refer to Section 5.4.e of this program solicitation for detailed instructions on the Company Commercialization Report.

If your proposal is selected for award, the technical abstract and discussion of anticipated benefits will be publicly released on the Internet; therefore, do not include proprietary or classified information in these sections. Note also that the DoD website contains timely information on firm, award, and abstract data for all DoD SBIR/STTR Phase I and II awards archived for several years. This information can be viewed on the DoD SBIR/STTR website.

The maximum dollar amount for a Phase I proof-of-concept/feasibility study is $150,000. **The CBD STTR Program will not accept Phase I proposals which exceed $150,000 for the Phase I effort (exclusive of Technical Assistance; see below)**. To maintain the total cost for STTR Phase I and Phase II activities at a limit of $1,150,000, the total STTR funding amount available for Phase II activities from a resulting Phase II contract will be $1,000,000 (also exclusive of Technical Assistance, if requested).

Companies submitting a Phase I proposal under this solicitation must complete the Cost Volume using the on-line form, within a total cost of $150,000 over a period of up to six months.

Selection of Phase I proposals will be based upon the evaluation criteria discussed in Section 6.0 of this program solicitation. The CBD STTR Program reserves the right to limit awards under any topic, and only those proposals of superior scientific and technical quality in the judgment of the technical evaluation team will be funded.

Companies should plan carefully for any research involving animal or human subjects, biological agents, etc. The short Phase I Period of Performance may preclude plans including these elements, unless coordinated before a contract is awarded.

If a small business concern receives an STTR award, the firm must negotiate a written agreement between the small business and their selected Research Institution that allocates intellectual property rights and rights to conduct follow-on research, development, or commercialization.

Proposals not conforming to the terms of this solicitation, and any unsolicited proposals, will not be considered. Awards are subject to the availability of funding and successful completion of contract negotiations. The Chemical and Biological Defense Program is not responsible for any funds expended by the proposer prior to contract award.

CBD Program Phase II Proposal Guidelines

Phase II is the demonstration of the technology that was found feasible in Phase I. The Reauthorization of the SBIR/STTR Program (see Note 1) has resulted in significant changes to the Phase II proposal submission process. Phase I awardees may submit a Phase II proposal without invitation; however, it is strongly encouraged that a Phase II proposal not be submitted until sufficient Phase I progress can be evaluated and assessed based on results of the Phase I proof-of-concept/feasibility study Work Plan and at a recommended five months from date of contract award. **All Phase II proposal submissions must be submitted electronically through the DoD SBIR/STTR Proposal Submission system at https://sbir.defensebusiness.org/.** At the proposal submission website, Phase II proposals MUST be submitted to '**CBD** STTR' regardless of which DoD contracting office negotiated the Phase I contract. Additional instructions regarding Phase II proposal submission process including submission key dates will be provided to Phase I awardees after Phase I contract award and also can be found at https://www.cbdsbir.net.

All proposers are required to develop and submit a commercialization plan describing feasible approaches for marketing and manufacturing the developed technology. Proposers are required to submit a budget for the entire 24 month Phase II period. During contract negotiation, the Contracting Officer may require a Cost Volume for a base year and an option year; thus, proposers are advised to be aware of this possibility. These costs must be submitted using the Cost Volume format (accessible electronically on the DoD SBIR/STTR submission site), and the two-years may be presented side-by-side on a single Cost Volume sheet. The total proposed amount should be indicated on the Proposal Cover Sheet as the Proposed Cost. At the Contracting Officer's discretion, Phase II projects may be evaluated for technical progress prior to the end of the base year, prior to extending funding for the option year.

The CBD STTR Program is committed to minimizing the funding gap between Phase I and Phase II activities. The CBD STTR Program typically funds a cost plus fixed fee Phase II award, but may award a firm fixed price contract at the discretion of the Contracting Officer.

Technical Assistance

In accordance with the Small Business Act (15 U.S.C. 632), the CBD STTR Program Office will authorize the recipient of a Phase I and/or a Phase II STTR award to purchase technical assistance services (Discretionary Technical Assistance, DTA), such as access to a network of scientists and engineers engaged in a wide range of technologies, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns as:

- making better technical decisions concerning such projects;
- solving technical problems which arise during the conduct of such projects;
- minimizing technical risks associated with such projects; and
- developing and commercializing new commercial products and processes resulting from such projects.

If you are interested in proposing use of a vendor for technical assistance, you must provide a cost breakdown in the Cost Volume under "Other Direct Costs (ODCs)" and provide a one-page description of the vendor you will use and the technical assistance you will receive. The proposed amount may not exceed $5,000 for Phase I and $5000 for each year of a Phase II project. The description should be included as the LAST page of the Technical Volume. This description will not count against the Phase I or Phase II proposal page limit and will NOT be assessed against STTR proposal evaluation criteria. Approval of technical assistance is not guaranteed and is subject to review of the Contracting Officer.

Key Dates

15.C Solicitation Pre-Release	27 August 2015 – 27 September 2015
15.C Solicitation Open/Close	28 September 2015 – 28 October 2015 (submission deadline: 6:00 am Eastern Time on closing date)
Phase I Evaluations	November – December 2015
Phase I Selections	No Later Than 27 January 2016
Phase I Awards	May 2016 (see Note 2)
Phase II Proposal Submission	Recommend proposal submission no earlier than approximately five months from date of Phase I contract award. Additional instructions regarding Phase II proposal submission process including key dates will be provided to Phase I awardees after Phase I contract award and also can be found at https://www.cbdsbir.net.

(Note 1) On December 31, 2011, the President of the United States signed into law the National Defense Authorization Act for Fiscal Year 2012 (Defense Reauthorization Act), Public Law 112–81. Section 5001, Division E, of the Defense Reauthorization Act contains the SBIR/STTR Reauthorization Act of 2011 (SBIR/STTR Reauthorization Act), which extends both the SBIR and STTR Programs through September 30, 2017.

(Note 2) Subject to the Congressional Budget process.

CBD STTR PROPOSAL CHECKLIST

This is a Checklist of Requirements for your proposal. Please review the checklist carefully to ensure that your proposal meets the CBD STTR requirements. **Failure to meet these requirements will result in your proposal not being evaluated or considered for award**.

_____ 1. The Proposal Cover Sheet along with the Technical Volume, Cost Volume, and Company Commercialization Report were submitted via the Internet using the DoD's SBIR/STTR Proposal Submission Web site at https://sbir.defensebusiness.org/.

_____ 2. The proposal cost adheres to the CBD STTR Program criteria specified.

_____ 3. The proposal is limited to only **ONE** solicitation topic. All required documentation within the proposal references the same topic number.

_____ 4. The Project Abstract and other content provided on the Proposal Cover Sheet does not contain any proprietary or classified information and is limited to the space provided.

_____ 5. The Technical Volume of the proposal includes the items identified in Sections 5.4.b and 5.4.c of this program solicitation.

_____ 6. The Phase I Proposal Technical Volume must be 20 pages or less in length. The Cover Sheet, Cost Volume and Company Commercialization Report do not count against the 20-page Proposal Technical Volume page limit. Pages in excess of this length will not be evaluated and will not be considered for review.

_____ 7. The Company Commercialization Report is submitted online in accordance with Section 5.4.e. This report is required even if the company has not received any prior STTR funding.

_____ 8. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

CBD STTR 15.C Topic Index

CBD STTR 15.C Topic Descriptions

CBD15C-001 TITLE: Infectious Disease Diagnostics and Differentiation of Viral vs. Bacterial Infections for Point of Care Applications

TECHNOLOGY AREA(S): Chemical/Biological Defense; Biomedical

OBJECTIVE: To provide an easy to use human clinical diagnostic testing technology which is effective for the detection, identification and differentiation of a wide range of viral and bacterial diseases caused by endemic diseases and biological warfare agents. Capabilities sought should be rapid and highly sensitive and selective solutions with low logistic burden for use in clinics and forward deployed military medical treatment facilities.

DESCRIPTION: The U.S. Department of Defense requires infectious disease *in vitro* diagnostic (IVD) capabilities that are operationally suitable for use in far forward military environments and operationally effective versus a wide range of threats. Current single use disposable Lateral Flow Immunoassay-based diagnostic tests have many desirable operational suitability characteristics (low cost, minimal training, lightweight, results in 15 minutes, eye readable results, and long shelf life at room temperature) but lack sufficient sensitivity to be clinically useful for most infectious diseases. Current nucleic acid amplification-based diagnostic tests provide adequate sensitivity for many diseases but are slow (>30 minutes), more complex, and have a high cost per test. Lastly, current approaches to detect and identify specific diseases on an individual disease basis do not provide adequate breadth of coverage to fully inform treatment and patient evacuation decisions at the far forward, tactical level of health care on the battlefield. A combination of approaches to individually or syndromically identify diseases for the most common endemic diseases for the deployed military population paired with broad category screening approaches (such as virus vs. bacteria) that would address non-prevalent diseases (such as diseases caused by most Biological Warfare Agents) would provide an informative, yet risk balanced approach to support individual patient treatment, troop evacuation to higher echelon treatment facility/return to duty decisions, and public health decision making.

To be affordable and supportable within the military healthcare system, diagnostic platforms must possess a broad range of capabilities for routine health care and endemic disease diagnostics while being a suitable platform for contingency use of Biological Warfare Agent and emerging disease IVD tests. For this reason, devices or companies with an existing catalog of FDA cleared tests for the U.S. domestic healthcare market and/or syndromic approaches to diagnostics are desired. Additionally, it is desirable for small business offerors to possess established quality management systems and regulatory affairs experience.

This topic seeks to develop novel approaches to provide practical patient diagnostics and screening capabilities at field deployment locations from least-invasive clinical sample types while maintaining desirable operational suitability characteristics.

PHASE I: Conduct proof of concept demonstrations of the specific technical approaches for disease diagnostics and screening (i.e., viral vs. bacterial infection differentiation) in symptomatic patients with high specificity (greater than or equal to 90%) for acute infections (testing occurs within the first 24 hours after symptom on-set) *in an operationally suitable platform.*

Use of human or animal subjects is not intended, or expected, in order to establish/achieve the necessary proof-of-concept.

The Government will provide a list of diseases and etiological agents of operational concern (Government Furnished Information (GFI)) to inform the Contractor's development of a technical approach. The primary emphasis will be for undifferentiated febrile illnesses. A subset is provided below for proposal development purposes:

- Influenza
- Pneumonic Plague
- Dengue
- Endemic typhus
- Scrub typhus

- Leptospirosis
- Chikungunya
- Lassa Fever
- Crimean-Congo Hemorrhagic Fever

The description of the technical approach entails a detailed description of assay designs (bio-recognition elements), signal amplification and transduction techniques, selected sample type, and sample preparation techniques (if any) for a specific diagnostic intended and the description of a proposed clinical trial design and the performers ability to complete product development an achieve FDA regulatory approval within 3-5 years. The description should describe how sufficient inclusivity and specificity will be obtained to inform treatment and/or reflex testing decisions. A phased approach to expanding the inclusivity and intended use over time will be acceptable. Provide an analysis of the envisioned technical approach with respect to the Clinical Laboratory Improvement Act (CLIA) guidelines for CLIA-waived status.

PHASE II: Develop and deliver prototype IVD device and pilot lot assays (if applicable to the system design) to the Government for independent evaluation. Complete pre-submission meetings with the FDA to inform inclusivity, specificity and syndromic approaches for the test and CLIA-waived clinical trial design. The degree of innovation will be measured by the offeror's ability to achieve a high clinical specificity for a broad range of disease while retaining operationally desirable characteristics (cost < $40 per sample analyzed, training time less than 4 hours, system weight with consumables for 40 tests less than 25 lbs., single sample time to result less than 30 minutes, eye readable results, and consumable shelf life greater than 1 year at 25C).

By the end of Phase II, the offeror will have produced a pre-production prototype of the diagnostic device, optimized the assay design for performance in the relevant clinical sample types, temperature and shelf life stability, and manufacturability and will be ready to begin pre-clinical trials shortly after Phase III award.

PHASE III: Complete the maturation of all hardware, software and reagent elements of the diagnostic device. Conduct pre-clinical and clinical trials and 510(k) package preparation and submission (as the sponsor) to the U.S. Food and Drug Administration (FDA) for the initial IVD product developed under Phase II. Conduct follow-on developments and FDA clearances of IVD tests for additional known and emerging diseases of operational interest to the U.S. Military. Manufacture IVD devices and assays (as applicable to the technical approach) under current Good Manufacturing Practices (cGMP) and other quality systems and deliver to the Government for operational use by Warfighters. The Government will provide Government Furnished Information (GFI) and Materials (GFM), when not publically available, to support assay design and testing. The Government will provide access to Biological Safety Level (BSL) 3 and 4 testing facilities when needed.

PHASE III DUAL USE APPLICATIONS: Beyond the diagnostic use for the military population, products of this effort are intended be used in U.S. and European Union domestic health care markets for in vitro diagnostics. Furthermore, for some disease tests, the products of this effort may be useful for companion diagnostics to be used in therapeutic development studies.

REFERENCES:
1. CLIA Categorizations (n.d.), retrieved December 2, 2014 from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393229.htm

2. Field Manual 4-02 Army Health System, August 26th 2013, retrieved Dec 17th from http://armypubs.army.mil/doctrine/DR_pubs/dr_a/pdf/fm4_02.pdf , pages 1-9, 7-7 and 7-8

KEYWORDS: infectious disease, in vitro diagnostic, point of care, biological warfare agent, biomarkers

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